

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

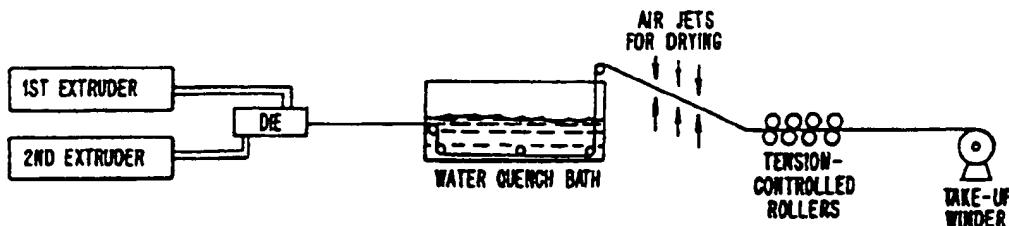
**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61C 15/04, A61K 7/16, D01F 8/06, 8/12, 8/14		A1	(11) International Publication Number: WO 98/06350 (43) International Publication Date: 19 February 1998 (19.02.98)
(21) International Application Number: PCT/US97/13802 (22) International Filing Date: 8 August 1997 (08.08.97)		Casper, W. [US/US]; 860 Turnini Drive, Danville, CA 94526 (US).	
(30) Priority Data: 08/699,891 15 August 1996 (15.08.96) US		(74) Agents: GALLOWAY, Peter, D.; Ladas & Parry, 26 West 61st Street, New York, NY 10023 (US) et al.	
(60) Parent Application or Grant (63) Related by Continuation US Filed on 08/699,891 (CON) 15 August 1996 (15.08.96)		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(71) Applicant (for all designated States except US): GILLETTE CANADA INC. [CA/CA]; 16700 Trans Canada, Kirkland, Quebec H9H 4Y8 (CA).		Published With international search report.	
(72) Inventors; and (75) Inventors/Applicants (for US only): TSAO, Belinda [CA/US]; 12020 Green Hills Court, Los Altos, CA 94022 (US). PARK, Edward, Hosung [US/US]; 28 Turning Mill Lane, Sharon, MA 02067 (US). ZWICK, Paul [US/US]; 4430 Eastwicke Boulevard, Stow, OH 44224 (US). DESAI, Pranav [US/US]; 5291 Rural Ridge Circle, Anaheim Hills, CA 92807 (US). TSENG, Mingchih, Michael [US/US]; 4 Partridge Drive, Hingham, MA 02043 (US). CHIANG,			

(54) Title: DENTAL FLOSS



(57) Abstract

Improved dental flosses are provided, comprising a coextruded, multicomponent, monofilament, viscoelastic floss having a first thermoplastic elastomer to provide strength to the floss and a second thermoplastic elastomer to provide desired surface properties to the floss.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LJ	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

- 1 -

DENTAL FLOSS

This invention relates generally to the field of filaments and extrusion methodology for producing such and more particularly relates to multicomponent floss materials and methods for producing such.

5 Tooth decay and dental disease can be caused by bacterial action resulting from plaque formation around the teeth and/or the entrapment of food particles in interstices between teeth. Removal of plaque and entrapped food particles reduces the incidence of caries, gingivitis, and mouth odors as well as generally improving oral hygiene. Conventional brushing has been found to be inadequate for
10 removing all entrapped food particles and plaque. To supplement brushing, dental flosses and tapes are used.

15 Monofilament, single component elastomeric fibers have been produced from various materials. When the material is soft enough for use as a floss, however, these monofilaments sometimes are not strong enough to withstand forces experienced during flossing, and are susceptible to shredding or tearing.

Dental flosses often include additives such as flavors or colors. These flavors have been conventionally applied by coating the additive onto the surface of the floss. Some dental flosses and tapes have been coated with waxes to aid in insertion of the floss or tape between the teeth.

20 Improved dental flosses are formed of a single filament that includes two or more coextruded thermoplastic elastomer ("TPE") components selected to provide desired properties to the floss. Manufacturing floss from two or more different TPE components can provide the floss with the desired characteristics of each component (e.g., good tensile strength, slipperiness, and comfort during use), which otherwise
25 might be unavailable from a single component. For example, in a core-and-sheath arrangement, the inner core TPE may provide greater tensile strength, viscoelasticity, resiliency and tear-resistance to the fiber than are available with the sheath material alone; the outer sheath material may provide a desired surface property, such as slipperiness or softness or abrasiveness, to improve ease of insertion, comfort/"mouth
30 feel" and cleaning capability, respectively, of the floss; either material may serve as a carrier for additives, such as flavors, scents and medicaments.

In a sheath-and-core arrangement, TPE components are selected to

- 2 -

ensure that the sheath and core are sufficiently adhered to each other so that separation during use is avoided. The monofilament's properties can be adjusted through properly blending different TPEs while retaining proper adhesion between the core and sheath. Adhesion may also be improved by varying the surface area of the core, or increasing 5 the number of filaments comprising the core.

When relaxed, the diameter of multicomponent TPE monofilament floss of the invention may be too large to insert between teeth for flossing. Due to the viscoelasticity of the TPE materials, however, the floss is capable of being stretched before use, thereby decreasing the diameter of the monofilament for easier insertion 10 between the user's teeth.

A further aspect of the invention features improved multicomponent dental flosses in which one or more of the components includes an additive, e.g., a color, fragrance, flavor or active ingredient, which is releasable from the floss.

The improved flosses of the invention can be made by a method which 15 includes (a) coextruding two or more TPE polymers through a multicomponent die to form a multicomponent filament of a specific geometry; and (b) treating the filament for use as a dental floss by, for example, creating a textured surface.

Alternatively, TPE gel can be applied to floss by pressure-coating or "pulltruding" the core filament(s) of one or more components, which can then also be 20 textured.

Additionally, the invention features methods of flossing the teeth of, e.g., a human, by inserting between two teeth a length of a dental floss of the invention.

Other features and advantages of the invention will be apparent from the 25 drawings, the following Detailed Description:

Fig. 1 is a schematic view of a horizontal production line for manufacturing a coextruded dental floss according to one embodiment of the invention.

Fig. 2 is a cross-sectional view of a spinneret usable to produce multicomponent, coextruded flosses of the present invention.

30 Fig. 2a shows the die-and-slot arrangement for producing the "islands-in-the-sea" tape embodiment.

Figs. 3a - 3d are cross-sectional views, taken radially, of multicomponent

- 3 -

coextruded filaments having cores with various cross-sections to increase the degree of adhesion between the core and sheath materials, either by increasing the surface area alone (Figs. 3a, 3e and 3f) or by also using mechanical interlocking structures (Figs. 3b and 3d).

5 Figs. 4 - 4f are cross-sectional views, taken radially, of a trilobal single component filament according to one embodiment of the invention, a trilobal multi-component filament having a sheath/core cross-section, a trilobal multi-component filament having a tipped cross-section, and filaments having four and six square bumps and four and six triangular bumps to create a textured surface, respectively.

10 Figs. 5a - 5d are cross-sectional views of various embodiments of a floss having core filaments embedded in a gel body: an 11 x 12 x 11 tape; an 11 x 12 x 11 rod; a rod floss having five distinct groups of eight core filaments each; and a floss having 39 filaments arranged in three concentric circles surrounding a single core filament all embedded in gel.

15 Figs. 6 - 6b are optical micrographs of "islands-in-the-sea" dental floss of the invention at 300X magnification.

Fig. 7 depicts a spiral-textured floss.

Fig. 8 depicts the equipment set-up used to conduct the fray test.

Before the present monofilament, multicomponent dental flosses and processes for extruding such are described, it is to be understood that the invention is not limited to the particular embodiments or extrusion methodologies described. Such floss components and methodologies may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting. Instead, the scope of the present invention will be established only by the appended claims.

It must be noted that as used in this specification and the appended claims, the singular forms "a", "an" and "the" include plural reference unless the context clearly dictates otherwise. Thus, for example, reference to "a polymer" includes mixtures of different polymers.

30 Unless defined otherwise all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or

- 4 -

equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference.

Definitions

5 By "multicomponent", we mean that the filaments have two or more components, each comprised of a different thermoplastic material; by "coextruded", we mean that at least two of the components are present in the form of substantially separate phases having a distinct interface between them, rather than being intermixed after simultaneous but separate extrusion. The filaments are preferably formed by
10 processes which are referred to in the art as "coextrusion", but the term "multicomponent coextruded", as used herein, encompasses filaments having the structure described herein which are manufactured by processes other than coextrusion. The term "dental floss", as used herein, is defined to include dental flosses, dental tapes, and similar articles, that are sized to be drawn between the teeth.

15 The dental flosses of the present invention include an inner core and an outer sheath of a soft polymer. The core includes a TPE and the outer sheath includes a different TPE.

Preferred core components include styrenic-based elastomeric copolymers. Examples include SEBS (Styrene-Ethylene-Butylene-Styrene), available
20 from Shell under the tradename KRATON®, and from Consolidated Polymer Technologies (CPT) under the tradename C-Flex; SEPS (Styrene-Ethylene-Propylene-Styrene), available from M.A. Hanna; and SPBS (Styrene-Propylene-Butylene-Styrene), available from Kuraray Co. Polyether block amides such as those available under the tradename PEBAX® from ELF Atochem may be used if combined with a styrenic-based copolymer, since pure PEBAX cores do not adhere well to gel sheaths.
25 Likewise, (i) polyurethane-based materials (thermoplastic urethanes (TPUs)), such as Tecoflex and Tecothane, both available from Thermedics Inc., Pellathan, available from Dow Chemical, and Elastollan, available from BASF, (ii) polyester-based TPEs, such as Hytrel available from DuPont, (iii) polyolefin-based TPEs, such as SARLINK
30 available from DSM Corp. and SANTOPRENE available from AES Corp., and (iv) caprylactam-based polyurethanes, do not adhere well to gel sheaths when in pure form. Thus, they should also be blended with a styrenic-based copolymer to ensure proper

- 5 -

adhesion. Examples of acceptable blended cores are Pellathan/Septon (a styrenic-based copolymer) commercially available from M.A. Hanna as HTE 2203, and a one: one blend of PEBAX MX1205/KRATON FG1901.

Styrenic-based copolymers are also preferred for the sheath material.

5 Preferable sheaths have a Shore A hardness of less than about 10. Preferred TPEs for the sheath that can be used include styrenic-based copolymers such as those available from GLS Corporation (Cary, Illinois) (e.g., LC 115-035B, based on KRATON G-1651); SEPS gel (such as XL0141-x), available from M.A. Hanna, and C-Flex.

The sheath layer may include one or more extenders to increase its softness. Styrenic block copolymers may be extended with a wide variety of materials, as is well known in the art. Suitable extenders include oils, waxes, resins, asphalts, and other polymers, including polyolefins (see, e.g., Technical Bulletin No. SC:1757-93, The Shell Chemical Company describing extenders for KRATON block copolymers). Preferred extenders for increasing the softness of the sheath TPE typically associate with the rubber phase of the copolymer, and include mineral oil (such as Britol, Hydrobrite or Duoprime), silicone fluid, low molecular weight polyethylene, and low molecular weight SEBS/SEPS.

A thermoplastic elastomer and extender are selected to provide a desired combination of softness and resistance of the sheath layer to tearing or abrasion when used. Preferably, the sheath layer material includes a sufficient amount of extender to reduce the Shore A hardness of the material to less than ten.

Various adhesion enhancers such as modifiers to help in processing (e.g. polyolefins), adhesives (e.g., EVA) or tackifiers (e.g., alpha-methyl vinyl styrene) may be added to either or both of the core and sheath TPEs to enhance the degree of adhesion at the interface therebetween. For example, functionalized (maleic anhydride-grafted) TPE (e.g., KRATON FG1901X, a maleic anhydride-grafted SEBS copolymer) can be added to either one or both of a harder core made of PEBAX MX1205 or Pellathan or Hytrel, and a softer sheath made of KRATON G6713 or other TPE material to improve adhesion. Low molecular weight SEBS can also be added to a TPU for better adhesion. Adhesion can also be improved by adding to the sheath layer a TPE chemically similar to the core material.

Examples of constituted gel materials that may be used with Hanna's

- 6 -

HTE 2203 core material are:

	Material	Hanna Gel XL0141-8 (%)	Hanna Gel XL0141-21 (%)	Hanna Gel XL0141-26 (%)
	Septon 4055 (SEPS)	16.8	16.8	16.6
5	Bristol 50T (High Mol. Wt. Mineral Oil)	80.0	--	--
	Irganox 1010 (antiox.)	0.1	0.1	0.1
	Irgafos 168 (antiox.)	0.1	0.1	0.1
10	Affinity PL 1880 (modifier: low MWPE)	3.0	3.0	--
	Duoprime 90 (mix)	--	--	41.5
	Duoprime 90 (inject)	--	--	41.5
	Kemamide E (used as an antiox.)	--	--	0.2
15	Hydrobrite 200 (mix)	--	40.0	--
	Hydrobrite 200 (side inject)	--	40.0	--

Depending upon the desired characteristics of the floss, it is generally preferred that the floss cross-sectional area has greater than 20% of its area attributed to the strengthening core component, with a preferred ratio or cross-sectional areas of about 50% core TPE to about 50% sheath TPE. Further, preferred flosses have an outer diameter of from about 0.04 to 0.14 inches. For example, a floss having a HTE 2203 core hardness of 65 Shore A and an SEPS sheath hardness of 0 Shore A should have a diameter of about 0.08. The softer the gel, the wider the floss may be without adversely affecting the user's ability to use the floss. The strength of monofilament floss increases as the core to sheath ratio increases, provided that the core TPE is

- 7 -

stronger than the sheath TPE. Whether a gel monofilament is suitable for flossing may be determined by focusing on tear strength and hardness of the monofilament and materials used, rather than solely on tensile strength of the resulting monofilament.

As the hardness of the core material (and therefore its strength and tear resistance) increases, the desirable outer diameter of the floss should decrease, and the ratio between core and sheath should decrease, to ensure proper insertion between a user's teeth. If the outer diameter and ratio remain as large as for softer core materials, then the floss cannot be stretched sufficiently to enable use of the material as a floss. For example, if the core TPE in a core/sheath arrangement has a Shore A hardness of greater than about 35, then the outer diameter of the monofilament should be less than about 0.07 inches and the core/sheath ratio should be about 20:80. However, if the core comprises multiple filaments and the sheath material has a hardness of <= 0 Shore A, then the outer diameter can be increased above 0.07 inches and can increase the core/sheath ratio above 20:80 to, for example, 50:50.

Typical flosses of the invention preferably have a Shore A hardness of less than about 10, an elongation at break of greater than about 300%. The floss resulting from combining the core and sheath materials typically can withstand repeated stretching at room temperature to at least twice its original length and will forcibly return to approximately its original length when the tensile force is removed.

TPE components used in the floss of this invention preferably have an elasticity above 200% and preferably above 300%. Preferable ranges of viscoelasticity are from about 300% to about 1200% for the core material and from about 700% to about 2000% for the sheath material.

The tear resistances of the core and sheath materials forming the floss are also important to prevent undue shredding or tearing of the floss during use. Sheath materials preferably have greater than about 30 pounds per linear inch ("pli"), and core materials preferably have greater than about 250 pli, using an ASTM die "C" tear test, ASTM No. D412 run at 23°C. and 20 in./min.

Tear resistance may also be determined by the fray test, which requires stretching the elastic floss to its maximum elongation, mounting the floss on a holder and repeatedly mechanically inserting the stretched floss between a pinch point created by two artificial "teeth". As depicted in Fig. 8, each "tooth" is mounted on a spring to

- 8 -

permit a certain amount of give in the apparatus. Both "teeth" are mounted on a single pivot point and are held together by a one pound force. Two sets of teeth were used, a blunt set having a smoothly rounded contact point, and a sharper set having a sharply angled contact points which was used for flosses that could withstand a high number of cycles on the blunt set. The force pushing the teeth together is calibrated by using a piece of nonstretchable material, such as nylon. The normal force measured by the instron to pull a piece of nonstretchable material from the blunt set of teeth was approx 1 pound. The number of cycles of insertion before breakage is indicative of the strength and abrasion resistance of the floss. Flosses preferably withstand more than about forty cycles of insertion and retraction between the blunt "teeth" before breaking.

Various combinations of TPEs are shown in the examples. It has been found that best results are achieved if both TPE materials are manageable around the same temperature, and have roughly the same viscosity at handling temperature. If the handling temperature for one TPE differ significantly from that of the other TPE (e.g., greater than about 50°F. difference), then processing problems can occur in making the multi-component blends. These problems include, for instance, non-even cross-sectional distribution of the core and sheath materials, oddly- or irregularly-shaped product, or ineffective coextrusion because one of the materials is too liquid at the operating temperature required for the other material to maintain its form.

Coextruded monofilament floss has also been produced with a reversed geometry: having the softer gel material form the inner core, surrounded by a thin sheath of the TPE component chosen for strength, elasticity and tear-resistance. For example, the sheath can be made of a PEBAK/nylon blend or polyurethane. These flosses, however, are not as desirable as when the sheath is made of a softer material, because of increased abrasion and less desirable mouth feel.

Texturing can be added to the surface of the floss. Texturing improves the feel of floss, and increases user satisfaction with the degree of cleaning achieved by the floss. For example, as shown in Figs. 4c-4f, various geometries of the cross-sectional areas of the monofilaments can be used, including square and triangular bumps. A textured surface increases the user's satisfaction with the floss because of the apparent increased cleaning ability of the floss.

Textured floss can also be created by knitting the core material to

- 9 -

produce a bulkier, more irregular surface on which gel is then applied, or, for a multiple filament bundle, by braiding or twisting the multiple filaments before gel-coating the bundle. See, for example, Fig. 7 depicting a twisted monofilament having a cross-section as shown in Fig. 4c.

5 Another alternative structure for creating a floss having a textured surface is to helically-wrap one or more fine filaments around either the floss core filament or core bundle of filaments, which is then covered with the sheath material, or around the entire floss, so that the wrap material is not concealed from the user's teeth. Since the wrap material (less than about 45 denier) is small in diameter when compared
10 to the floss' diameter (for this embodiment, less than about 0.02 inches), its only purpose being to create an irregular surface, the material must have a higher tensile strength than the core material and must be capable of holding its geometry during use. Nylon has been used successfully for this purpose.

Preferred flosses may also have a "multilobal" cross-section, as shown in
15 Fig. 4. Preferred filaments include from 3 to 8 "lobes"; one suitable filament has 3 "lobes," as shown in Figs. 4-4b. The filaments are preferably formed by extrusion through a die having the appropriate "multilobal" cross-section. Multicomponent filaments having this cross-sectional configuration may have a sheath/core (Fig. 4a), tipped (Fig. 4b), or other suitable cross-section.

20 Apart from texturing concerns, the sheath and core may have any suitable cross-section, preferably a symmetric sheath/core cross-section (Fig. 3b) or an eccentric sheath/core cross-section (Fig. 3a). Alternatively, the floss may have a side-by-side arrangement (Fig. 3) or a pie cross-section. (Fig. 3d). Multifilament arrangements are also possible, such as depicted in Figs. 5a-5d ("islands-in-the-sea"),
25 and figures depicting the "islands-in-the-sea" and coated multifilament embodiments as disclosed in the U.S. Patent Application entitled "'Satin' Dental Floss," filed concurrently herewith. These arrangements permit increased adhesion between the core and sheath materials by increasing the surface area across which the materials are in contact.

30 Adhesion can also be improved between core and sheath materials either by varying the geometry of a single core to increase the surface area of contact between the core and sheath materials, as disclosed in Figs. 3a, 3e and 3f, and by

- 10 -

creating mechanical interlocking structures between the core and sheath materials, as disclosed in Figs. 3b and 3d. A separate adhesive layer may also be included between the gel sheath and core to ensure adhesion between the two. Inclusion of such a layer, however, increases the complexity of manufacturing such a floss.

5

Additives

The described preferred embodiments can be formulated to include one or more additives, e.g., a color, flavor, or active ingredient, in one or more of the components of the floss. For example, the sheath layer may contain an abrasive for improved cleaning such as kaolin, clay, and silica, or flavors and pigments to flavor 10 and color the floss. Examples of such additives are chlorhexidine (or a salt thereof), sodium fluoride, flavor (e.g. Polyiff®, or peppermint oil, from International Flavors and Fragrances Co. or Quest International Fragrance Inc.), fragrance, tooth desensitizer, tooth whitener, pigments, e.g., titanium dioxide, to impart color to the floss, or 15 antioxidants, to prevent discoloration, or other additives suitable for use in dental flosses such as antimicrobial agents. The preferable TPE for carrying the additive will be determined by the additive used, as would be readily appreciated by one skilled in the art.

The additive-containing component(s) may be water-soluble, to allow the additive to leach from the floss during use. The additive may also be provided as 20 supplied, in microencapsulated form, or adsorbed or absorbed onto another additive, e.g., a particulate filler. Flavoring, for example, can also be released through a floss by incorporating the fluid into a floss with a tubular core.

The additive, if desired, can be incorporated in encapsulated form. Encapsulation may be used for thermal protection or moisture protection of the 25 additive, and may be accomplished by any number of conventional techniques, such as spray drying spray-chilling, drum drying or solvent evaporation.

Advantageously, additives in liquid and/or encapsulated form can be incorporated into the flosses of the invention during manufacture of the filaments, rather than applying the additives later during separate coating steps. This not only 30 reduces the number of processing steps, but also reduces the amount of additive needed.

How flavor oils, for example, are added to the floss depends on whether the materials in the floss are susceptible to breakdown by the oils, all as known in the

- 11 -

art. Some materials, such as polyether polyurethanes and KRATON, are not attacked by flavor oils. Liquid flavors can therefore be dip-coated or sprayed directly onto the floss itself without concern about the floss' integrity, all as appreciated by one skilled in the art.

5 A preferred method for forming a dental floss of the invention is shown schematically in Fig. 1. First, two or more TPEs are coextruded through a two-component extrusion die. The polymers are chosen to produce a floss having the desired physical properties and/or the relative cross-sections, as described above. Preferred outer diameters of the holes in the die are from about 0.04 to about 0.14
10 inches. The die block is fitted with heater probes and a thermocouple. The heater is set at a temperature sufficient to avoid solidifying both TPEs. Suitable temperatures for the die block to permit the TPEs to easily flow can be determined empirically for a particular elastomer or elastomer/extender blend.

15 The filament exiting the die then passes through a water quenching chamber. The orientation of the die will dictate the location of this chamber. If the coextrudate exits the die horizontally (as depicted), then the water quenching chamber will be located directly downstream as close as possible to the spinneret, to minimize the opportunity for the horizontally-disposed filament to deform before quenching due to gravity. If the coextrudate is produced in a vertical stream, however, then
20 deformation of the molten polymer stream due to gravity is not as great a concern, and the water bath may be placed further away, although still preferably less than two feet from the die. The monofilament fiber is guided under low tension from the extruder through the quench chamber and, upon exiting the bath, is passed over a series of tension-controlled rollers before being wound-up under low tension. The speed of the
25 tension rollers controls the size of the final filaments. Preferred speeds of travel of the fiber through the above process are from roughly 150 feet per minute for commercial processing. No draw-down is necessary for these filaments.

30 Twisted flosses as shown in Fig. 7 may be produced by twisting the hot molten extrudate before setting in the cold water bath. Alternatively, post-coextrusion treatment of the floss by heating to approximately 250°F., twisting, and then setting in cold water will produce the same result.

Crimped or embossed floss may be produced by passing the hot

- 12 -

extrudate, before quenching in the water bath, through an opposing set of chilled and motorized aluminum wheels containing a textured groove. The depth of the groove is roughly half that of the extrudate, so that grooves in two opposed wheels permit the floss to pass through and be textured without substantial deformation. Patterns etched
5 into the grooves transfer to the extrudate as it passes through the grooves while being quenched. Patterns may take any form although cross-hatched or screw-type impressions are preferred. The speed of the wheels should be set to match the extrusion speed. The wheels should be coated with teflon, or wet with water to prevent the hot extrudate from sticking to the wheels.

10 Alternatively, if the floss is to be crimped after the floss has already been cooled, then a heated (up to around 100°F.) grooved wheel may be used, after which the floss is requenched. The small amount of heat is sufficient to soften the outer layer of the floss to permit crimping.

15 If floss is braided or knitted, soft sheath material can be coated in a layer thin enough so that the outer surface of the floss has a geometry corresponding to the outer surface of the braided or knitted portion.

In another embodiment of the invention, multiple filaments of one or more components are extruded as taught in the U.S. Patent Application entitled “
‘Satin’ Dental Floss,” filed concurrently herewith. For example, multiple filaments of
20 Elastollan are extruded, water-quenched, and heat drawn in a 2:1 ratio to orient the individual filaments. SEPS gel is then pressure-coated, or “pulltruded,” onto the surface of the horizontally-oriented bundle by drawing the filaments through a single-hole die to which the SEPS gel is applied. Preferred bundles of multiple filaments have 144, 96 or 48 filaments.

25 Finally, floss may be packaged in any manner. One preferred manner is to package approximately six-inch relaxed lengths of the floss in a gas-impermeable material to maintain sterility and prevent excessive evaporation of the flavor oils. The package is attached at either end of the floss, so that when the packaging is torn, the package ends provide useful tabs for the user to hold while flossing. Another manner
30 is to package the floss under low-tension on a small bobbin.

Examples

The following examples are put forth so as to provide those of ordinary

- 13 -

skill in the art with a complete disclosure and description of how to make the monofilament flosses and carry out the extrusion methodology of the invention, and are not intended to limit the scope of what the inventors regard as their invention. Efforts have been made to ensure accuracy with respect to numbers used (e.g., amounts, 5 temperatures, etc.) but some experimental errors in deviation should be accounted for.

The following description of an equipment set-up and manufacturing procedure is representative of that used to create the flosses described. Two 1.25-inch diameter extruders were connected to a two-component extrusion die with metering pumps on each screw operating to deliver the flowrate of material to the die to form a 10 floss having a ratio of 50:50 core material:gel material. The two-component extrusion die included a metering plate, a distributing plate, etched plates, and a spinneret/ die. Operating temperatures of the equipment and molten materials were recorded at various stages before leaving the die. After being coextruded through the extrusion die according to standard methods, the extrudate was processed with a downstream filament 15 spinning set-up to produce floss. The downstream set-up included a quenching water bath, tension-controlled rollers and a winder.

Using the equipment set-up and procedures described above, the following specialty bicomponent, monofilament flosses were formed, which exhibited improved mechanical properties over a single component "gel" monofilament:

- 14 -

Example No.:	1	2
Date of Run	06/17/96	03/07/96
Cross-section	34 islands/sea rod; Fig. 6b	34 islands/sea tape
Core Component	TPU/KRAT. HTE 2203	TPU/KRAT. HTE 2203
5 Sheath Comp.	SEPS gel XL0141-8	GLS G6713 KRATON
Ratio (Sheath/Core)	50/50	50/50
Sheath O.D./ Core O.D. (in.)	Rod 0.08" O.D.	0.0065" x 0.372"
10 Metering Pumps (size (cc)/speed (rpm))	6 cc / 5 rpm both	6 cc / 3 rpm both
Temp. of Core mat'l at die exit (°C.)	201	199
15 Temp. of Sheath mat'l at die exit (°C.)	205	200
Temp. of Spin Head (°C.)	210	203
20 Winder Speed (mpm)	20	Manual wind
Fray Test (avg. of 5 runs)	147+/- 8 Blunt	197 Blunt; 3.2+/- 0.2 Sharp
Tensile strength (kg)	3.1 +/- 0.1	not measured
Comments	--	15 mm x 0.17 mm slot die; vertical extrusion

- 15 -

	Example No.:	3	4
	Date of Run	02/14/96	01/26/96
	Cross-section	Core/sheath	Core/sheath tube; Fig. 4c
	Core Component	Hanna HTE 1113 (Shore A 66 SBS)	PEBAX MX1205 / KRATON FG1901 1:1 blend
5	Sheath Comp.	GLS LC115-035B	GLS LC 115-035B
	Ratio (Sheath/Core)	80/20	80/20
	Sheath O.D./ Core O.D. (in.)	0.07" / 0.032"	0.060" / 0.032" tube 0.020"
10	Metering Pumps (size / speed (rpm))	1 amp/19.5 rpm for sheath mat'l; no melt pump for core mat'l	1 amp/19.5 rpm for sheath mat'l; no melt pump for core mat'l
	Temp. of Core mat'l at die exit (°C.)	not measured	not measured
15	Temp. of Sheath mat'l at die exit (°C.)	not measured	not measured
	Temp. of Spin Head (°C.)	182	182
20	Winder Speed (mpm)	22.3 ft/min.	approx 22 ft./min.
	Fray Test (avg. of 5 runs)	24 +/-1 Blunt	62 +/- 10 Blunt

- 16 -

	Example No.:	5
	Date of Run	03/07/96
	Cross-section	Multiple Bicomponent Filaments
	Core Component	Hanna TPU/KRATON blend HTE 2203
5	Sheath Comp.	GLS KRATON G6713
	Ratio (Sheath/Core)	30/70
	Sheath O.D. / Core O.D. (in.)	--
	Metering Pumps (size (cc) / speed (rpm))	6cc / 2.4 rpm (sheath) 6cc / 5.6 rpm (core)
	Temp. of Core mat'l at die exit (°C.)	196
10	Temp. of Sheath mat'l at die exit (°C.)	197
	Temp. of Spin Head (°C.)	203
	Winder Speed	hand-wound
	Fray Test (avg. of 5 runs)	96 filaments: 32+/-2 cycles (Sharp) 48 filaments: 37+/-3 cycles (Sharp)

15

Other embodiments are within the claims. For example, while bicomponent monofilaments have been described above in the Detailed Description; the filaments could contain any desired number of components, and in this case would be manufactured by extrusion through a suitable multicomponent die using the appropriate number of extruders.

20

- 17 -

C L A I M S

1. A multicomponent, monofilament, viscoelastic dental floss comprising a core composed of a first thermoplastic elastomer and a sheath encasing said core composed of a second, different thermoplastic elastomer, the difference of the melting points of said first and second thermoplastic elastomers being less than about 30°C., said floss having a Shore A hardness of less than about 10 and an ultimate elongation of greater than about 300, said floss having a tear resistance of greater than about 40 cycles on a blunt-toothed fray test.
2. The dental floss of claim 1, wherein at least one of the core and sheath thermoplastic elastomers comprises a styrenic-based block copolymer.
3. The dental floss of claim 2, wherein said block copolymer is blended with another material, said blend improving the chemical affinity between the core and sheath elastomers.
4. The dental floss of claim 3, wherein said blend is selected from the group consisting of polyurethane/styrenic-based block copolymer, polyamide/styrenic-based block copolymer, polyester/styrenic-based block copolymer, polyolefin/styrenic-based block copolymer, or maleicanhydride modified styrenic-based block copolymer.
5. The dental floss of claim 4, wherein the block copolymer is selected from the group consisting of styrene-ethylene-butylene-styrene, styrene-ethylene-propylene-styrene, styrene-propylene-butylene-styrene, styrene-isoprene-styrene, and styrene-butadiene-styrene copolymers.
6. The dental floss of claim 1, wherein the sheath further comprises an extender to increase the softness of said sheath.
7. The dental floss of claim 6, wherein the extender is selected from the group consisting of oils, waxes, resins and asphalts.
8. The dental floss of claim 1, wherein said first elastomer of said core is selected to provide strength to the floss, and said second elastomer of said sheath is selected to provide a surface having at least one predetermined physical characteristic.
9. The dental floss of claim 1, wherein one or more of the elastomers of the floss includes an additive.
10. The dental floss of claim 9, wherein the additive is selected from the group consisting of colors, fragrances, flavors, therapeutically-active ingredients, and

- 18 -

modifiers which improve the adhesion between the elastomers of the core and sheath.

11. The dental floss of claim 10, wherein said modifier is selected from the group consisting of functionalized thermoplastic elastomers, thermoplastic elastomers having the same block copolymer structure as the thermoplastic elastomer in the corresponding portion of said floss, tackifiers, or adhesives.
12. The dental floss of claim 9, wherein the additive is incorporated into the floss in a manner to allow it to be released from the floss during use.
13. The dental floss of claim 1, wherein said core comprises one or more components different from a component of said sheath.
- 10 14. The dental floss of claim 1, wherein said first elastomer of said core has a viscoelasticity in the range of from about 300% to about 1200%, and said second elastomer of said sheath has a different viscoelasticity in the range of from about 300% to about 2000%.
15. The dental floss of claim 1, wherein said core has geometrically-enlarged surface area to increase adhesion between the core and the sheath.
16. The dental floss of claim 15, wherein said core has a cross-sectional shape that is multi-lobed, multi-petaled, multi-spiked or multi-spoked.
17. The dental floss of claim 1, wherein said core has geometrically-enlarged surface area that comprises means for interlocking the core and sheath for enhancing adhesion therebetween.
- 20 18. The floss of claim 1, having a cylindrical cross-section with an outer diameter of from about 0.04 inches to about 0.14 inches.
19. The floss of claim 1, having a textured outer surface.
20. The floss of claim 19, wherein the floss is twisted.
- 25 21. The floss of claim 19, wherein said textured surface is created by multiple protrusions.
22. The floss of claim 19, wherein said textured surface is created by helically-wrapping a relatively small-diameter filament around said floss at a radial distance at least as large as the outer diameter of said core.
- 30 23. The floss of claim 19, wherein said textured surface is created by imprinted regular indentations or crimps.
24. The floss of claim 1, wherein said core has a tubular cross-section along

- 19 -

substantially its entire length.

25. A multicomponent, monofilament, viscoelastic dental floss comprising a plurality of continuous cores having a first thermoplastic elastomer and a body sheath substantially adhered to and substantially surrounding each of said cores along substantially the entire lengths thereof comprising a second thermoplastic elastomer, the difference of the melting points of said first and second thermoplastic elastomers being less than about 50°F., said floss having a Shore A hardness of less than about 10 and an ultimate elongation of greater than about 300, about 300, said floss having a tear resistance of greater than about 40 cycles on a blunt-toothed fray test.

10 26. The dental floss of claim 25, wherein said plurality of continuous cores are arranged in multiple groupings of cores spaced throughout the floss' cross-sectional area.

27. The dental floss of claim 26, wherein said multiple groupings comprise five offset groupings of eight cores each.

15 28. The dental floss of claim 26, wherein said multiple groupings of cores comprise multiple offset rows.

29. The dental floss of claim 28, wherein said multiple offset rows comprise three offset rows of 11, 12 and 11 cores.

30. The dental floss of claim 26, herein said multiple groupings comprise 20 multiple concentric circles.

31. The dental floss of claim 30, wherein said multiple concentric circles comprise 1, 8, 12 and 18 cores.

32. A method of making a multicomponent, monofilament, viscoelastic dental floss of claim 1, comprising the steps of:

25 coextruding two or more thermoplastic elastomers through a multi-component die assembly to form coextrudate comprising said at least one core having said first thermoplastic elastomer and said sheath comprising said second thermoplastic elastomer; and

quenching said coextrudate.

30 33. The method of claim 32, wherein at least one of the core and sheath thermoplastic elastomers comprises a styrenic-based block copolymer.

34. The method of claim 33, wherein said block copolymer is blended with

- 20 -

another material before extrusion, said blend improving the chemical affinity between the core and sheath elastomers of said dental floss.

35. The dental floss of claim 34, wherein said blend is selected from the group consisting of polyurethane/styrenic-based block copolymer, polyamide/styrenic-based block copolymer, polyester/styrenic-based block copolymer, polyolefin/styrenic-based block copolymer, or maleicanhydride modified styrenic-based block copolymer.

5 36. The method of claim 35, wherein the block copolymer is selected from the group consisting of styrene-ethylene-butylene-styrene, styrene-ethylene-propylene-styrene, styrene-propylene-butylene-styrene, styrene-isoprene-styrene, and styrene-

10 butadiene-styrene copolymers.

37. The method of claim 32, further comprising adding an extender to the sheath elastomer before extrusion to increase the softness of said sheath.

38. The method of claim 37, wherein the extender is selected from the group consisting of oils, waxes, resins and asphalts.

15 39. The method of claim 32, wherein said first elastomer of said core is selected to provide strength to the floss, and said second elastomer of said sheath is selected to provide a surface having at least one predetermined physical characteristic.

40. The method of claim 32, further comprising the step of incorporating an additive into one or more of the elastomers before or during coextrusion.

20 41. The method of claim 40, wherein the additive is selected from the group consisting of colors, fragrances, flavors, therapeutically-active ingredients, and modifiers which improve the interfacial adhesion between the elastomers of the core and sheath.

25 42. The method of claim 41, wherein said modifier is selected from the group consisting of functionalized thermoplastic elastomers, thermoplastic elastomers chemically similar to the thermoplastic elastomer in the corresponding portion of said floss, tackifiers, or adhesives.

30 43. The method of claim 32, wherein said die assembly creates said at least one core having geometrically-enlarged surface area to increase adhesion between the core and the sheath.

44. The method of claim 43, wherein said core has a cross-sectional shape that is multi-lobed, multi-petaled, multi-spiked or multi-spoked.

- 21 -

45. The method of claim 43, wherein said core has geometrically-enlarged surface area that comprises means for interlocking the core and sheath for enhancing adhesion therebetween.
46. The method of claim 32, further comprising texturing the outer surface
5 of said floss.
47. The method of claim 46, wherein said textured surface is created by helically-wrapping a relatively small-diameter filament around said quenched coextrudate.
48. The method of claim 46, wherein said textured surface is created by
10 imprinting regular indentations or crimps on the surface of the molten floss before the coextrudate is quenched.
49. The method of claim 46, wherein said textured surface is created by heating the surface of the quenched floss, imprinting regular indentations or crimps on the surface of the molten floss, and requenching the floss.
- 15 50. The method of claim 46, further comprising twisting the textured floss.
51. A method of making a multicomponent, monofilament, viscoelastic dental floss of claim 24, comprising the steps of:
 - 20 coextruding two or more materials through a multicomponent die assembly to form coextrudate comprising said plurality of cores having said first thermoplastic elastomer embedded in said sheath comprising said second thermoplastic elastomer; and
 - quenching said coextrudate.
52. A method of flossing teeth by inserting between two teeth a length of multicomponent, monofilament, viscoelastic dental floss comprising at least one core
25 comprising a first thermoplastic elastomer, and a sheath comprising a second thermoplastic elastomer.

1/8

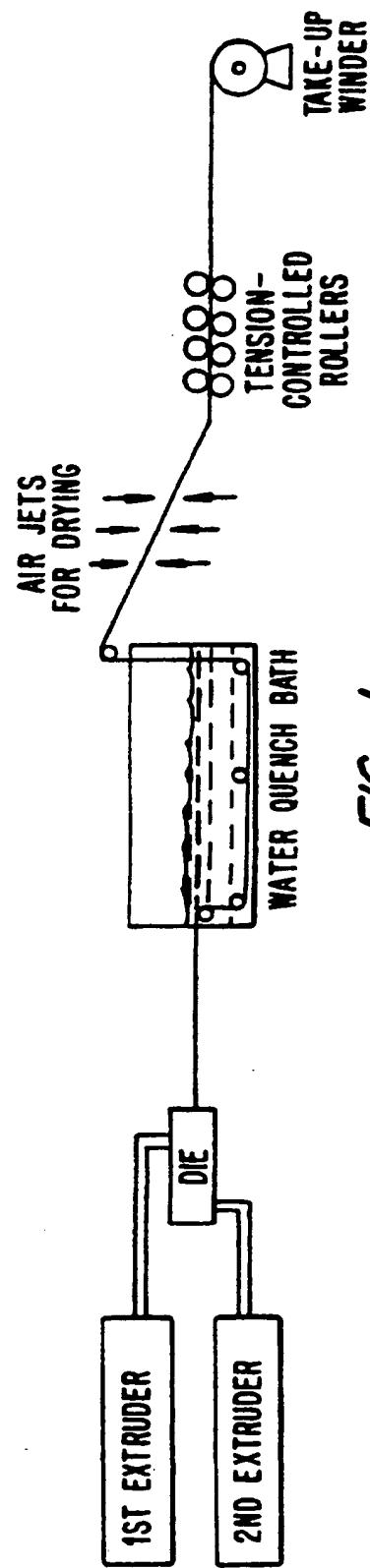


FIG. 1.

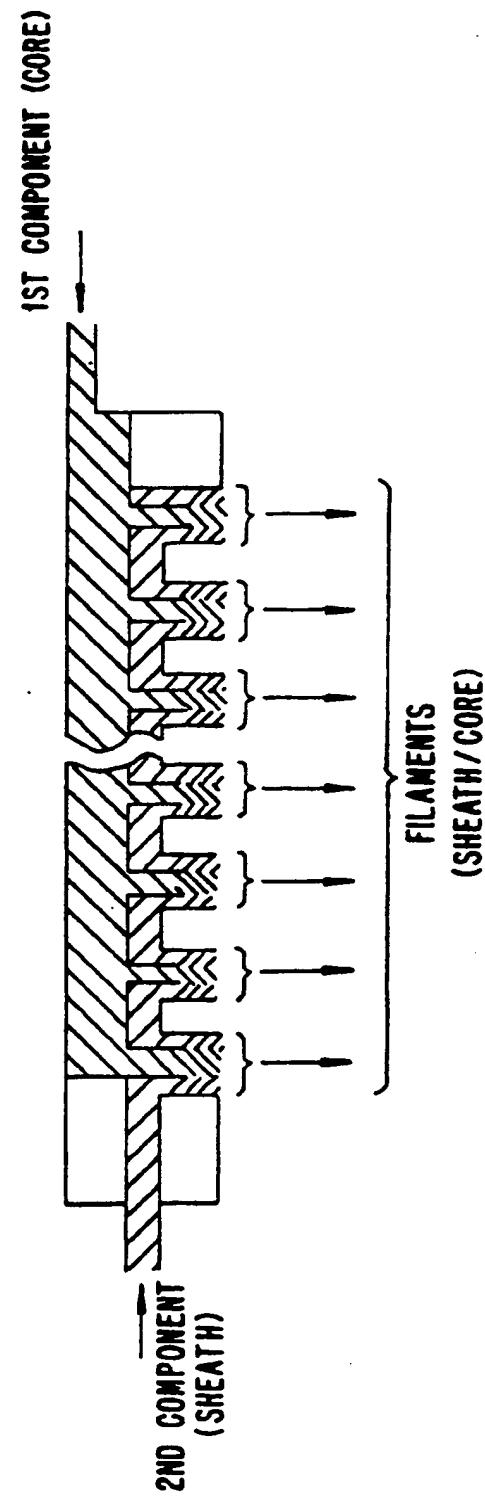


FIG. 2.

2 / 8

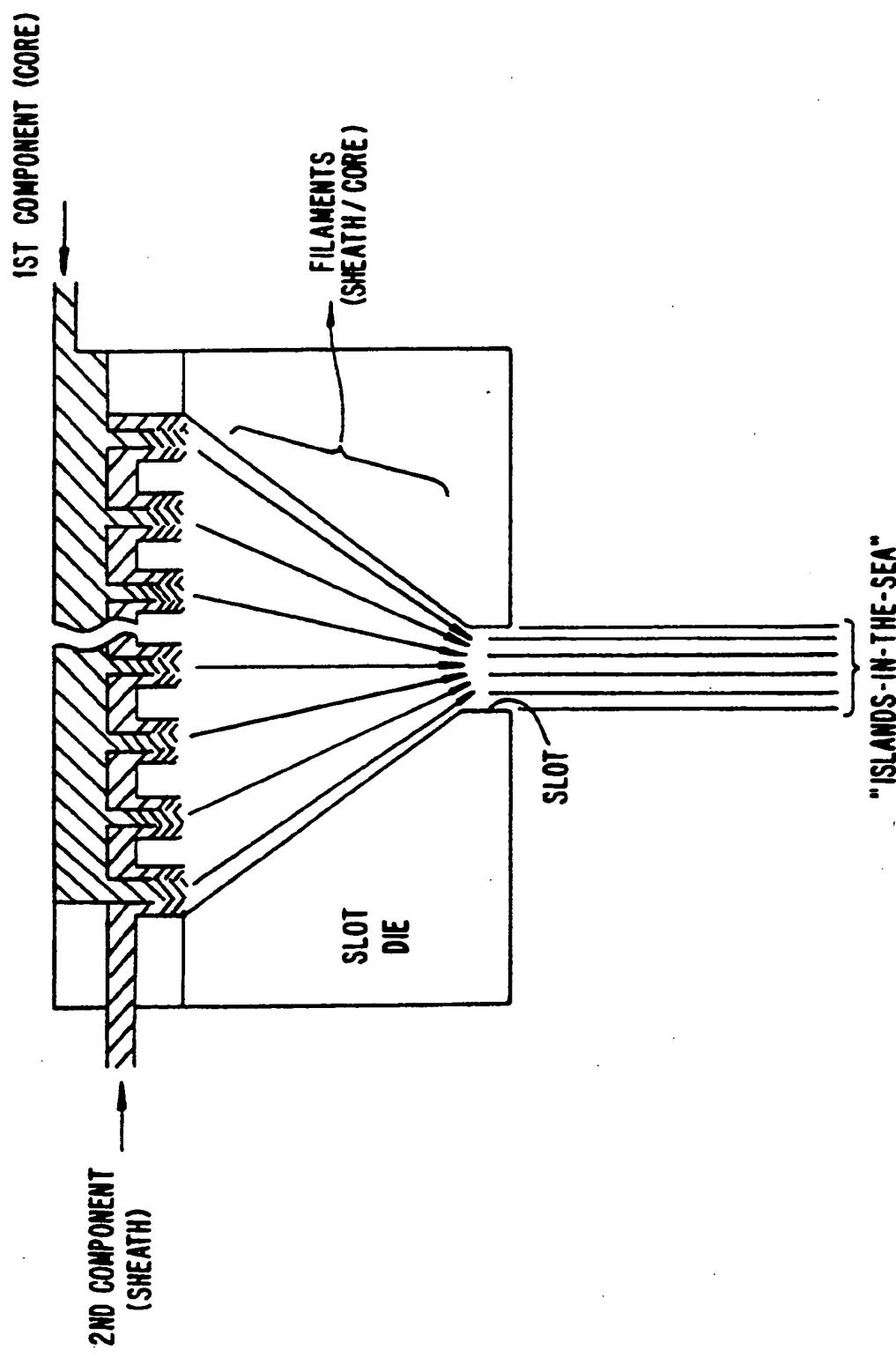


FIG. 2A.

SUBSTITUTE SHEET (RULE 26)

3 / 8

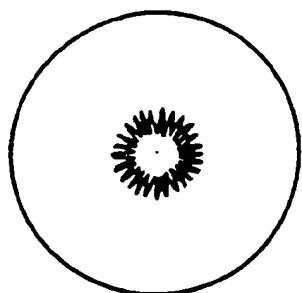


FIG. 3A.

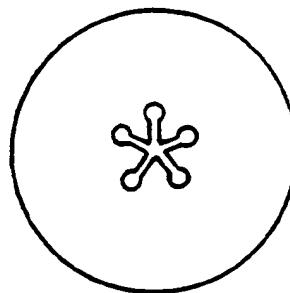


FIG. 3B.

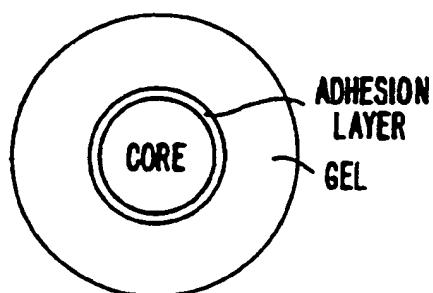


FIG. 3C.

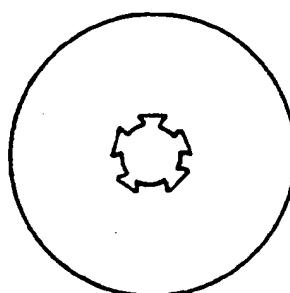


FIG. 3D.

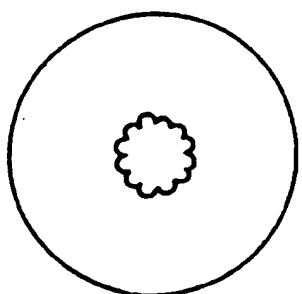


FIG. 3E.

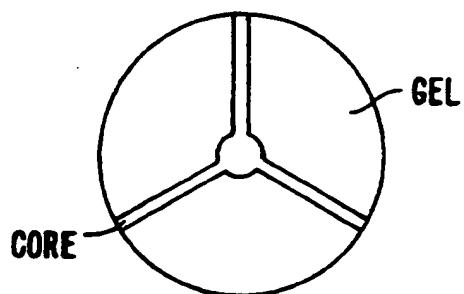


FIG. 3F.

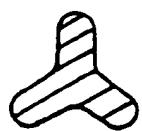


FIG. 4.

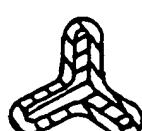


FIG. 4A.

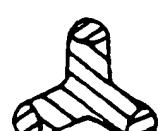


FIG. 4B.

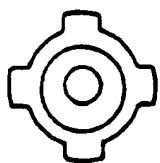


FIG. 4C.

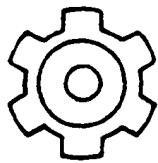


FIG. 4D.

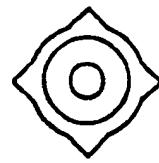


FIG. 4E.

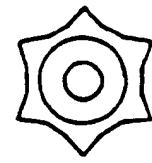


FIG. 4F.

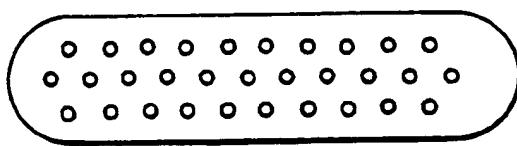


FIG. 5A.

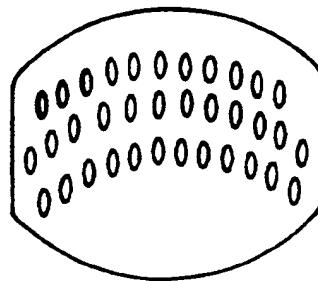


FIG. 5B.

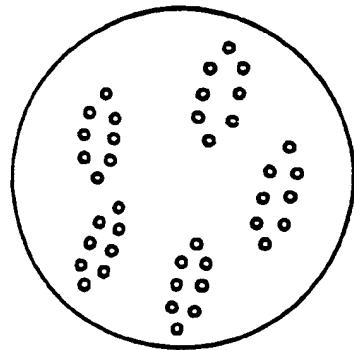


FIG. 5C.

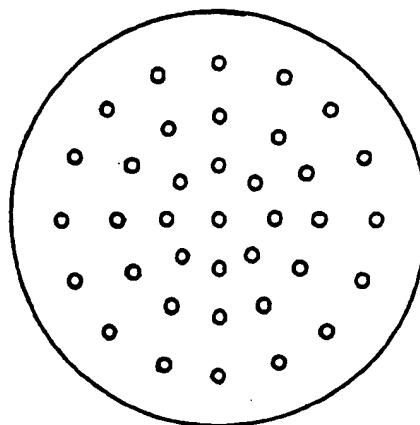


FIG. 5D.

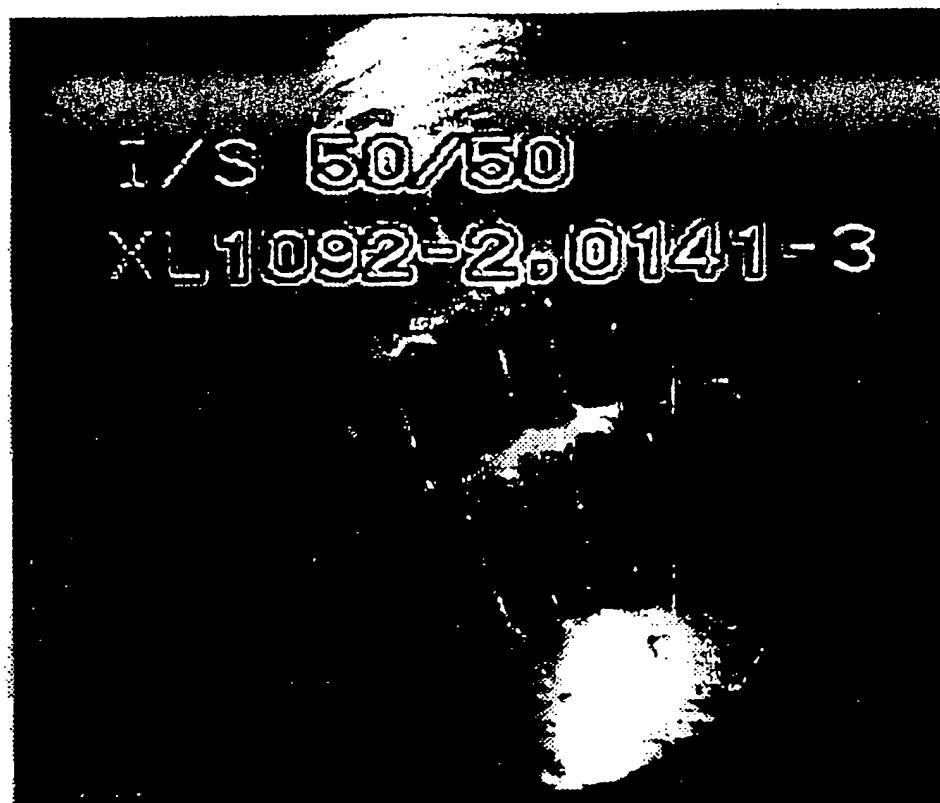


FIG. 6.

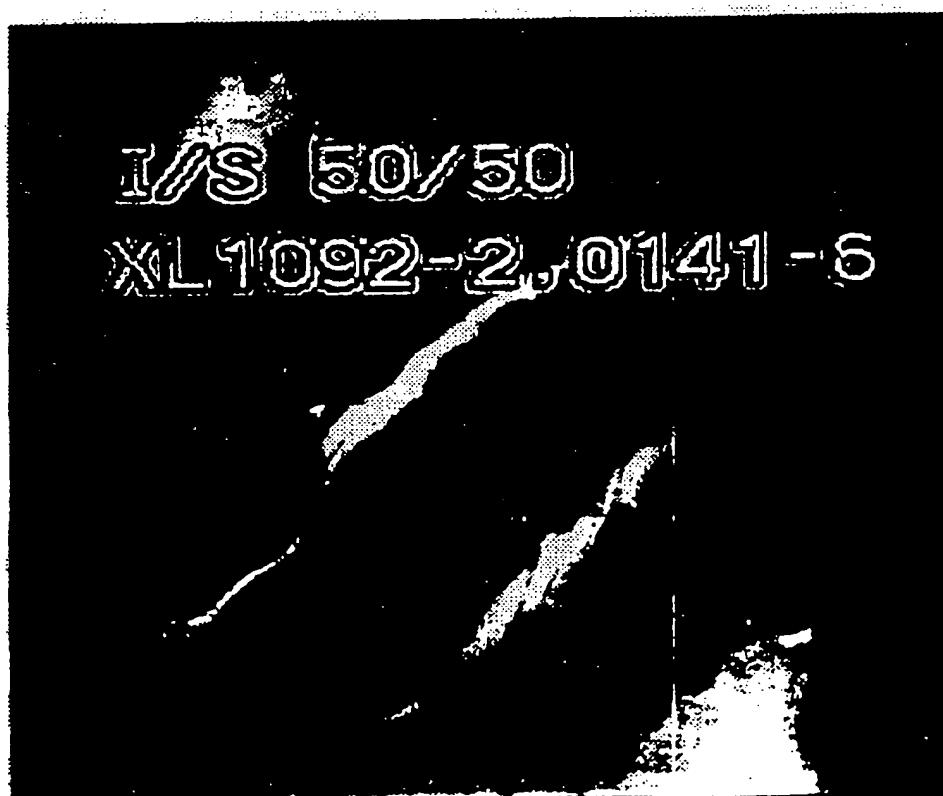


FIG. 6A.

6 / 8



FIG. 6B.

7/8

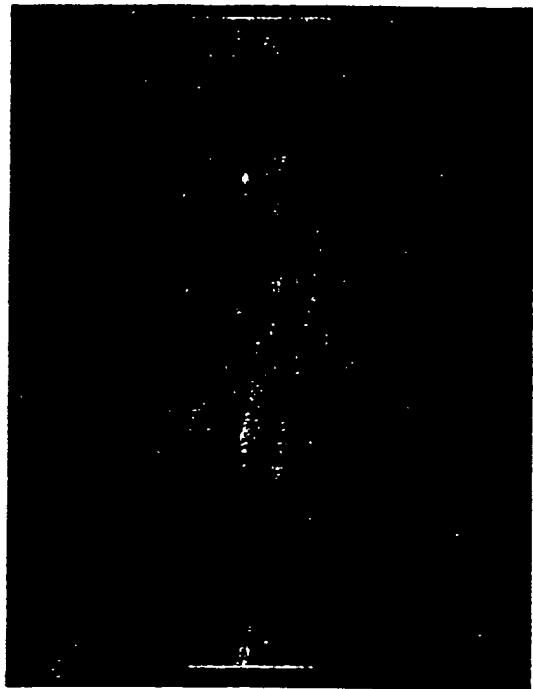


FIG. 7

SUBSTITUTE SHEET (RULE 26)

8/8

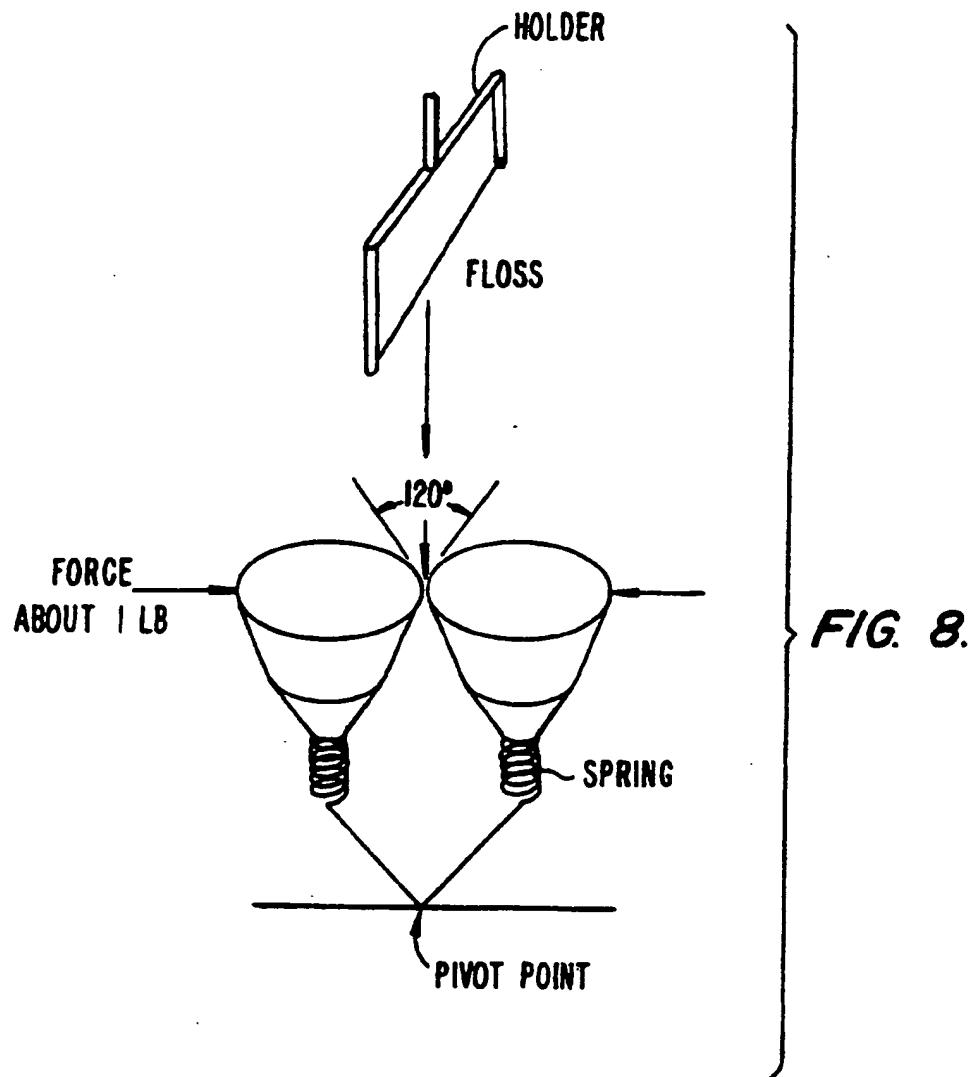


FIG. 8.

INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 97/13802A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61C15/04 A61K7/16 D01F8/06 D01F8/12 D01F8/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61C A61K D01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 583 564 A (FINKELSTEIN PAUL - ET AL) 22 April 1986 see column 1, line 67 - column 2, line 52 see column 3, line 17 - line 21 ---	1-15, 17-25, 32-43, 45-52
Y	US 5 262 468 A (CHEN JOHN Y) 16 November 1993 see column 4, line 65 - column 5, line 3 see column 6, line 43 - line 63 see column 7, line 28 - line 33 --- -/-	1-15, 17-25, 32-43, 45-52

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

1

Date of the actual completion of the international search

17 October 1997

Date of mailing of the international search report

28.10.97

Name and mailing address of the IBA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 851 epo nl
Fax: (+31-70) 340-3016

Authorized officer

Chabus, H

INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 97/13802

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 798 216 A (MCCARTY JOHN D ET AL) 17 January 1989 see column 1, line 25 - line 41 ---	1,8-12, 15,16, 19,21, 23,25, 32,37-52
A	WO 93 02633 A (GILLETTE CANADA) 18 February 1993 see page 5, line 11 - line 14 see page 6, line 17 - line 28 see figure 1 ---	1,25-32, 51,52
A	EP 0 686 390 A (JOHNSON & JOHNSON CONSUMER) 13 December 1995 ---	
P,X	WO 96 39117 A (GILLETTE CANADA ; TSENG MINGCHIH M (US); MASTERMAN THOMAS CRAIG (US) 12 December 1996 see page 3, line 25 - line 35 see page 4, line 32 - page 5, line 1 see page 11, line 28 - line 31 see page 14, line 9 - line 14 see figures 2-4B -----	1,6-25, 32,37-52

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No

PCT/US 97/13802

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 4583564 A	22-04-86	NONE		

US 5262468 A	16-11-93	US 4369284 A		18-01-83
		US 5153254 A		06-10-92
		US 4618213 A		21-10-86
		US 5475890 A		19-12-95
		US 5624294 A		29-04-97
		US 5508334 A		16-04-96
		US 5633286 A		27-05-97
		US 5239723 A		31-08-93
		US 5336708 A		09-08-94
		US 5334646 A		02-08-94
		US 5655947 A		12-08-97
		US 5324222 A		28-06-94

US 4798216 A	17-01-89	NONE		

WO 9302633 A	18-02-93	US 5226435 A		13-07-93
		AU 663107 B		28-09-95
		AU 2412292 A		02-03-93
		BR 9206322 A		04-04-95
		CA 2114415 A		18-02-93
		EP 0597005 A		18-05-94
		MX 9204484 A		01-02-93
		US 5357990 A		25-10-94

EP 0686390 A	13-12-95	AU 2046995 A		07-09-95
		BR 9502683 A		05-03-96
		CA 2151022 A		07-12-95
		JP 8038513 A		13-02-96
		PL 308949 A		11-12-95

WO 9639117 A	12-12-96	AU 6255696 A		24-12-96
